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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,550	02/24/2004	Bernd Thureau	MDX / 291US	8154
26875 7590 11/12/2008 WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202				
EXAMINER NGUYEN, HUONG Q				
ART UNIT		PAPER NUMBER		
3736				
MAIL DATE		DELIVERY MODE		
11/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/785,550

Applicant(s)

THURAU ET AL.

Examiner

HELEN NGUYEN

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.

4a) Of the above claim(s) 8-9, 17-19, 44-45, 51, 60-61, 67-81, 89-90, 97-98, 101, 106, and 108-112 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7, 10-16, 20-43, 46-50, 52-59, 62-66, 82-88, 91-96, 99, 100, 102-105, 107, 113 and 114 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the reply filed 8/4/2008. Claims 1-114 are pending. Claims 8-9, 17-19, 44-45, 51, 60-61, 67-81, 89-90, 97-98, 101, 106, and 108-112 remain withdrawn. **Claims 1-7, 10-16, 20-43, 46-50, 52-59, 62-66, 82-88, 91-96, 99-100, 102-105, 107, and 113-114** remain under prosecution.
2. It is noted that this application contains claims 8-9, 17-19, 44-45, 51, 60-61, 67-81, 89-90, 97-98, 101, 106, and 108-112 drawn to an invention nonelected with traverse in the reply filed on 9/14/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-7, 10-16, 20-29, 34, 37-43, 46-50, 58-59, 62-66, 82-88, 91-92, 95-96, 99-100, 103-105, and 113-114** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US Pat No. 4673386) in view of Alden et al (US Pub No. 20050101979), further in view of Hagen et al (US Pat No. 6348043).

5. **Claims 30-33, 35-36, 52-57, 93-94, 102, 107** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Alden et al and Hagen et al, further in view of Bazell et al (US Pat No. 4370987).
6. **Claims 1-7, 10-16, 20-29, 34, 37, 82-88, 91-92, 95-96, 99-100, 103-105, and 113** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al (US Pub No. 20050101979) in view of Hagen et al (US Pat No. 6348043).
7. **Claims 30-33, 35-36, 93-94, 102, 107** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Bazell et al (US Pat No. 4370987).
8. **Claims 38-43, 46-50, 58-59, 62-66, and 114** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Simpson et al (US Pat No. 5002066).
9. **Claims 52-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Simpson et al, even further in view of Bazell et al.
10. Please refer to the Office Action dated 3/4/2008 for complete details.

Response to Arguments

11. Applicant's arguments filed 8/4/2008 have been fully considered but they are not persuasive. Applicant contends that there is explicit teaching away from modifying Gordon by replacing the rigid piston with a flexible membrane of Alden because Gordon teaches a rigid bottom on the piston so as not to attenuate or alter the pressure of the fluid in the fluid line and replacing said piston with just a flexible membrane would prevent such. While it is true that such consideration should be maintained, it is noted that the combination of both Alden and Hagen as motivated by the reasons elaborated in the outstanding rejection make obvious a substitution of the piston of Gordon for a flexible membrane mechanism actuated by the piston of Hagen because the simple substitution of one known element for another is obvious to one of ordinary skill in the art when such substitution would have obtained predictable and desired results in the functioning of the reservoir due to the well known function of both structures. It is also noted as previously stated in the outstanding rejection, Alden explicitly teaches that said flexible membrane 310 can be actuated by mechanical means (§0025), thus providing solid motivation for the use of a piston such as that taught by Hagen.

12. Applicant also contends that modifying Gordon at least with Alden would represent a major shift in the principle of operation of the reservoir because Gordon's system is rigid such that if the piston is pulled back too quickly, the negative pressure maybe be sufficient to collapse the patient's artery while the more passive-pull of the flexible membrane of Alden creates a gentler negative pressure and further provides some give that prevents or reduces the likelihood of collapsing the artery of the patient (remarks p.31-32). However, as explicitly pointed out by Applicant, it is believed that such positive effects of the use of the flexible membrane of Alden

over the rigid piston of Gordon only further provides motivation to one of ordinary skill in the art to modify the reservoir of Gordon by Alden by providing such advantageous features to the reservoir, namely reducing the likelihood of collapsing a patient's artery. It is noted that such advantage does not change the principle of operation of Gordon because the reservoir would not only function in the same manner and allow the sampling of blood but also provide additional advantages and thus work better.

13. Still, Applicant contends that the combination of Gordon, Alden, and Hagen does not result in the reservoir as claimed because the Examiner has supposedly ignored the teaching of Hagen that the flexible membrane is carried by and secured along the periphery of the piston. While it is agreed that Hagen does teach this, and it is also noted that Applicant's own invention appears to have such features, it is unclear how such teaching would not result in the reservoir as claimed. In fact, it is believed that the combination of the above references would make obvious the reservoir as claimed, as motivated by the reasons elaborated in the outstanding rejection.

14. Lastly, Applicant contends that Alden does not teach flow through the chamber between the inlet 304 and the exit port 312 when the diaphragm 310 is in a minimum volume position. However, it is noted that such argument assumes that "a minimum volume position" is defined as "the minimum volume position." It is noted that "a minimum volume position" may be defined by Alden as one where there is simultaneous fluid communication between said inlet port, exit port, and the chamber and as such allows flow through the chamber between the inlet and exit port as claimed. It is noted that Applicant has not specifically defined what a minimum volume position is and as such has been defined in the manner above, i.e. a minimum volume position as compared to the expanded maximum volume position. Furthermore, it is noted that the

combination of Gordon, Alden, and Hagen would provide for the limitation of flow through the chamber of Gordon between the inlet and the exit port 17, 19 of Gordon when the flexible membrane of Alden is in a minimum volume position.

15. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736

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